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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/721,168	11/22/2000	R. Terry Dunlay	97,022-G1	5283

7590 10/03/2003

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EXAMINER	
CHEU, CHANGHWA J	

ART UNIT	PAPER NUMBER
1641	10

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/721,168	Applicant(s) DUNLAY ET AL.	
	Examin r Jacob Cheu	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *13-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Objections

1. Claim 14 is objected to because of the following informalities: in line 2, "change *the in* distribution" is grammatically erroneous. It is suggested that applicants replace with "change *in the* distribution." Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 20 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 20, steps (i) and (ii) recite fluorescent signals in a "field". It is unclear what is the field and its relationship to the fluorescent imaging.

With respect to claim 27, line 3, "chemical environment" is vague and indefinite. It is unclear what constitutes "chemical environment" in the claim language.

With respect to claim 27, line 1, "detecting an effect of the test compound on *one* or more of the following:", whereas the claim recites *two* effects, including "chemical environment" *and* "enzymatic activity". It is suggested that applicants change line 3, "and", to "or" for clarity.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 13-20, 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morrison Dennis (USP 5869238) in view of Walt et al. (USP 6210910).

Morrison teaches a method of evaluation of tumorigenic metastasis by using fluorescent flow cytometry and digital image analysis. (See abstract) Morrison teaches using fluorescent markers in measuring the distribution of membrane bound tumor marker, i.e. urokinase, versus the cytoplasmic urokinase level and correlates with DNA (nuclei) contents by digital image analysis. (Col. 6, line 19-26) Morrison also teaches using secondary antibody for determining enzymatic activity or other biochemical functions by using different wavelengths simultaneously measuring nuclei DNA content, membrane bound and cytoplasmic proteins. (Col. 4, line 7-12; Col. 6, line 61-67) Furthermore, the

teachings of Morrison can be applied to monitoring on the cancer treatment, i.e. potential test compounds for post-operative treatment (Col. 4, line 32-36) However, Morrison does not specifically teach applying an array of multiple cells for mass measurement. Walt et al. teach fluorescent image scanning of an array of samples in a plurality of microwells. (See Abstract, Figure 8) Walt et al. teach that such microanalysis of the living biological samples offers the advantages in high throughput screening for potential pharmaceutical compounds. (Col. 5, line 42-50) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the method of Morrison with the array of the microwells as taught by Walt et al., since it is well-desired for an economical and time-saving fashion in applying high throughput techniques in clinical and/or basic research settings.

7. Claims 21-23 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morrison in view of Walt as applied to claims 13-20 above, and further in view of Johnson Gary (USP 5857786).

Morrison and Walt et al. references have been discussed but do not specifically applying the recited method to measure the GTP-binding protein families, such as Rho protein, GTP binding protein, and tyrosine kinase. Johnshon reviews the importance of cell cycle in regulating cell growth as well as migration, and teaches a method of measuring the GTP-binding protein family proteins, such as Rho, GTP-binding protein, and tyrosin kinase for identifying compounds capable of regulating cell cycle process by using digital imaging analysis. (See Abstract, claims 1-6; Col. 20, line 22-29) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the methods of Morrison and Walt et al. with the cell cycle target proteins as taught by Johnson, since it is a long-felt need to discover the regulating process of cell cycle in treatments of certain diseases involving cell cycle or migration abnormalities.

8. Claims 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morrison and Walt et al. in view of Johnson as applied to claims 13-23 above, and further in view of Kris et al. (USP 6238869).

Morrison, Walt and Johnson et al. references have been discussed but fail to specifically teach measuring tyrosine kinase protein, such as src. Kris et al. teach fluorescent microarray to screen target molecules to study gene expression, or physiological responses to pathogen, or development of a disease. (Col. 35-45) One of the target molecules measured by Kris et al. is the tyrosine kinase src which is responsible for phosphorylation on the cellular proteins. (Col. 16, line 1-8) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the method of Morrison, Walt and Johnson with the target molecule src tyrosine kinase as taught by Kris et al., since src tyrosine kinase is a well-known target molecule for phosphorylation on the cellular protein substrate for various physiological regulation and pathological development.

Conclusion

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 703-306-4086. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3399.

Jacob Cheu
Examiner
Art Unit 1641

September 30, 2003

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
09/03/03